

REMARKS

Claims 1-28 and 30 are pending. To expedite prosecution, the composition and method of claims 1 and 4 have been amended to specifically recite a mixture or mixing of a polypyrrolic macrocyclic photosensitizer and at least one triblock copolymer. This amendment is supported at least on page 11, lines 11-12 of the specification. Other amendments are supported at page 30, lines 23-27. Thus, no new matter is added. Applicants address the rejections in view of the amended claims.

Rejections under 35 U.S.C. § 112

Claims 1-28 and 30 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The claims have been amended for clarity, where the phrase “upon hydration with an aqueous medium” refers to the complex formed upon hydration. Accordingly, Applicants respectfully request that these rejections be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1-28 and 30 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Schneider (U.S. patent no. 6,258,378) alone or in combination with McCarty (U.S. patent 4,125,503) and Young (U.S. patent no. 6,375,930). The Office acknowledges that Schneider discloses formulations in combination with polymers, where the formulations lack a photosensitizer as a therapeutic or diagnostic agent. (Office action, page 2). However, the Office alleges that one of ordinary skill would be motivated to use Schneider’s composition to deliver a photosensitizer in view of McCarty and Young. (Office action, pages 2-3). Applicants respectfully disagree.

First, there is no motivation to combine Schneider, McCarty and Young because the subject matter in these references relate to non-analogous art. More particularly, Schneider and Young relate to compositions drug delivery systems. In contrast, McCarty teaches ultraviolet curing emulsion systems for use as a coating. (See abstract, and Example 1, particularly at col. 5:44-50 describing application of emulsion on a metal panel until a coalesced film is formed).

Second, even if combined, the combination fails to teach the invention as claimed. Schneider is silent regarding polypyrrolic macrocyclic photosensitizers, and teaches compositions having a final formulation that does not comprise a triblock copolymer carrier agent such as PLURONIC® emulsion systems. The surfactants in Schneider are only used to facilitate lipid solubilization and gas microbubble formation, and are removed after microbubble formation. (See, U.S. patent 6,258,378 at col. 13:6-8). Young describes texaphyrin-lipophilic conjugates, and is also silent regarding triblock copolymer carrier agents.

Thus, even if combined, Schneider and Young fail to teach a composition comprising a triblock copolymer carrier agent, and methods of formulating the same. This failure to teach the invention as claimed is not remedied by the combination with McCarty, which fails to teach the use of polypyrrolic macrocyclic photosensitizers. Furthermore, McCarty teaches UV-curable aqueous emulsions for coating compositions, and teaches away from dried photosensitizer-carrier compositions.

Based on the above, claims 1-28 and 30 are not obvious under Schneider, McCarty and Young. Applicants therefore, respectfully request that this rejection be withdrawn.

Claims 1-20, 16-28 and 30 are also rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable under McCarty in combination with Klaveness (U.S. patent 5,674,468). The Office acknowledges that McCarty fails to teach the preparation of a composition in a dried form in the presence of solid supports. However, the Office alleges that the preparation of McCarty's emulsion in dry form using lactose as a solid support would have been obvious since Klaveness teaches such a procedure to stabilize the composition. (Office action, page 2). Applicants respectfully disagree.

There is no motivation to combine McCarty and Klaveness because the subject matter is non-analogous. As previously indicated, McCarty relates to ultraviolet curing emulsion systems used as a coating. In contrast, Klaveness describes contrast agents comprising gas-containing or gas-generating polymer microparticles and/or microballoons, for use in imaging and diagnostic systems. (See Abstract and col. 1:13-24).

Furthermore, even if combined, the combination fails to teach the invention as claimed. Klaveness is silent regarding photosensitizers, let alone polypyrrolic macrocyclic photosensitizer compounds. Klaveness is also silent regarding compositions comprising a triblock copolymer carrier agent. As in Schneider, the PLURONIC® surfactant in the Klaveness patent is used only during the preparation of microparticles. Particles from oligomers (*i.e.*, beads) were collected after centrifugation of a suspension mixture. The beads were subsequently suspended in water and lactose, and freeze-dried into a block containing the beads frozen in a water and lactose mixture. (See, U.S. patent 5,674,468 at col. 40:26-45). Thus, even if combined, the combination fails to teach a dried photosensitizer-carrier composition comprising a polypyrrolic macrocyclic photosensitizer and a triblock copolymer carrier agent.

Based on the above, claims 1-10, 16-28 and 30 are not obvious under McCarty and Klaveness. Applicants therefore, respectfully request that this rejection be withdrawn.

Claims 1-10, 16-28 and 30 are also rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over McCarty, in view of Desai (U.S. Patent No. 6,074,666) or Madden (U.S. Patent No. 5,389,378) in further combination with Unger (U.S. Patent No. 6,028,066). The Office acknowledges that McCarty does not teach the preparation of a composition in a dried form in the presence of solid supports such as lactose, and the use of claimed photosensitizers. However, the Office alleges that the use of sugars and lyophilization of the preparations of McCarty would have been obvious because Unger teaches the advantages of lyophilized compositions. The Office further alleges that the use of sugars would also be obvious according to Madden, and that sugars are routinely added in freeze-dried preparations containing photosensitizers according to Desai. (Office action, pages 4-5). Applicants respectfully disagree.

Again, there is no motivation to combine McCarty, Desai, Madden and Unger because of non-analogous subject matter. Desai, Madden and Unger all relate to pharmaceutical compositions while McCarty relates to coatings. Furthermore, the combination of McCarty, Desai or Madden, in further combination with Unger fails to teach the invention as claimed. The liposome compositions in Desai and Madden do not comprise a triblock copolymer carrier agent. Unger describes prodrugs comprising fluorinated amphiphiles, and is silent regarding photosensitizers. The poloxamers (*e.g.*,

triblock copolymer carrier agents) described in Unger are used only for stabilizing or modifying gas and/or gaseous precursors that are incorporated in stabilizing materials and/or vesicles. (See U.S. patent 6,028,066 at col. 40:32 through col. 41:12; col. 45:40-57). Thus, even if combined, the combination fails to teach the invention as claimed.

Further, there is no reasonable expectation of success that the combination will result in the invention as claimed. As indicated in the specification, photosensitizers such as porphyrin- and benzoporphyrin (green porphyrin) derivatives) have a high tendency to aggregate. (See specification at page 1, line 30 through page 2, line 2). B-ring compounds have a greater tendency to undergo self-aggregation and lower solubility compared to A compounds. The use of various homopolymeric systems such as PVPs and PEGs has also proved unsuccessful in preventing aggregation in B-ring compounds. (Specification at page 2, line 30 through page 3, line 2; and page 3, lines 5-7). Thus, the present invention meets many of the needs in the art.

Based on the above, claims 1-10, 16-28 and 30 are not obvious under McCarty, Desai or Madden. Applicants therefore respectfully request that this rejection be withdrawn.

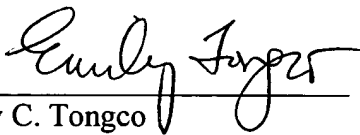
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012011700. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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